SECTION 2.0 – 510(k) SUMMARY

September 24, 2014

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical
340 Lake Hazeltine Dr.
Chaska, Mn 55318
FDA REGISTRATION NUMBER: 2126666

Telephone: 952-448-5111
Fax: 952-448-3441
Contact Person: Mathew Pexa,
Title: Regulatory Specialist II

2.2 DEVICE TRADE NAME / PROPRIETARY NAME

Mandrel Guidewires or M-Wires

2.3 DEVICE COMMON NAMES / USUAL NAMES / CLASSIFICATION NAMES

ENDOSCOPE AND ACCESSORIES (OCY); 21 CFR Part 876.1500

2.4 CLASS OF DEVICE

These devices are **Class II**.

2.5 IDENTIFICATION OF PREDICATE DEVICE(s)

K011084	Mandrel Guidewires (Lake Region Medical)
K080508	Mandrel Guidewires (Lake Region Medical)

2.6 DEVICE DESCRIPTION

The Mandrel wire family is made of a coated (PTFE or Silicone) or uncoated Nitinol or Stainless Steel core wire that is tapered at the distal tip where a coil is secured to the distal end. The distal coil can be anywhere from 2cm to 30cm depending on specific design and can consist of Stainless Steel, Palladium, Platinum, or the proposed Tungsten materials. The guidewire may contain proximal core markers. The Mandrel guidewire family is bound by the following parameters:

Lengths:	20cm to 500cm
Outside Diameter:	0.014” To 0.35”
Tips:	Straight or shaped with various flexibilities
Coil Length:	2cm to 30cm

2.7 COMPLIANCE WITH APPLICABLE STANDARDS

LRM has determined that no mandatory standards, performance standards, or special controls have been established for these devices under Section 514 of the Medical Device Amendments to Federal Food, Drug, and Cosmetic or by any subsequent regulatory action. However, the following standards are referenced within this filing: ISO 10993, ISO 11070, ISO 11135.

2.8 INTENDED USE STATEMENT

Mandrel Guidewires are intended to facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

NOTE: This modification does not alter its intended use.

2.9 CONTRAINDICATIONS

There are no contraindications listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

Lake Region Medical
Mathew Pexa
Regulatory Specialist II
340 Lake Hazeltine Drive
Chaska, MN 55318

Re: K140482
Trade/Device Name: Mandrel Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: March 11, 2014
Received: March 12, 2014

Dear Mathew Pexa,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K140482

DEVICE NAME: Mandrel Guidewire

INDICATIONS FOR USE:

Mandrel guidewires are intended to facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

PRESCRIPTION USE *(Part 21 CFR 801 Subpart D)*	X	*AND/OR*	**OVER-THE-COUNTER USE** *(21 CFR 807 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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2.10 TECHNOLOGICAL CHARACTERISTICS

The design specifications are substantially equivalent to the existing Mandrel Guidewires. Material used for the coil of the guidewire will include the addition material option of Tungsten.

2.11 QUALITY SYSTEM CONTROL

DESIGN CONTROLS

LRM is in conformance with the design control procedure requirements as specified in 21 CFR Part 820.33. Risk analysis was completed by means of a Failure Mode and Effects Analysis and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

MATERIALS / SUPPLIER / PRODUCT / PROCESS CONTROLS

LRM has formal quality systems in placed to assure that each product manufactured remains equivalent to the predicate products, and that the changes will not have an adverse effect on safety or effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Supplier Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size / group.

2.12 QUALIFICATION TESTING

The conclusions drawn from bench testing and biocompatibility testing demonstrate compliance with the design input summary which shows the device is at least as safe and effective as the current legally marketed device.

BENCH TESTING

In order to demonstrate equivalence of the guidewire, Lake Region Medical performed bench testing to establish requirements. Test devices were manufactured and inspected according to established requirements for visual/tactile, dimensional and mechanical attributes. The devices were then subjected to the following test methods to show the devices comply with the design input summary:

- Visual
- Radiopacity
- Lubricity
- J-Memory Test
- Body Stiffness
- Adhesion / Durability
- Guidewire Pull test
- Torque Strength
- Torque Control
- Dimensional
- Linear Stiffness
- Lateral Stiffness
- Particulate Test
- ISO Strength of Union
- ISO Flex Test
- ISO Corrosion Resistance Test
- ISO Fracture Test
- Hydrodurability

BIOCOMPATIBILITY TESTING

Biocompatibility testing per the design input summary requirements show the addition of Tungsten to the device does not affect the biocompatibility of the device and the device is still in compliance with pre-defined acceptance criteria outlined in the product Design Input Summary. A biocompatibility risk assessment determined the following biocompatibility tests are required:

- Cytotoxicity
- Hemolysis

2.13 SUBSTANTIAL EQUIVALENCE DATA

The addition of Tungsten to the Mandrel guidewire family does not change the indications for use of the Mandrel guidewires and is not a change to the fundamental scientific technology. The information summarized above shows the device will perform as well as the previously marketed device.